UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE VICAL INCORPORATED SECURITIES LITIGATION

Case No. 13-cv-2628 BAS (RBB)

Consolidated with: 13-cv-2653 BAS (RBB)

ORDER:
(1) GRANTING DEFENDANTS' MOTION TO DISMISS; and
(2) TERMINATING AS MOOT DEFENDANTS' MOTION TO STRIKE AND RELATED *EX PARTE* APPLICATION

[ECFs 39, 37, 48]

This action arises from two related securities class-action lawsuits brought on behalf of stockholders in Vical Incorporated. These actions were consolidated into the current matter on February 26, 2014. ECF 26. Lead Plaintiff Jack Roscoe, on behalf of the prospective class, filed a Consolidated Complaint on April 3, 2014, then a First Amended Complaint ("FAC") on May 12, 2014. ECF 32, 35. In response, Defendants Vical Incorporated, Jill M. Broadfoot, Anthony A. Ramos, and Vijay B. Samant filed motions to dismiss the FAC and to strike allegations

relating to confidential witnesses. ECFs 39, 37.

Having heard oral argument and reviewed all the moving papers in this case, the Court **GRANTS** Defendants' motion to dismiss and **TERMINATES** Defendants' motion to strike as **MOOT**.

I. BACKGROUND

Plaintiff brings this putative class action against Defendants, alleging Defendants Vical Incorporated ("Vical") and its officers, Jill M. Broadfoot, Anthony A. Ramos, and Vijay B. Samant committed securities fraud. Vical, a publicly-traded pharmaceutical research company, developed a potential drug ("Allovectin") to treat advanced cases of melanoma. Allovectin showed promising results in Phase II trials, and therefore Vical worked with the FDA to design a testing protocol to proceed to Phase III trials. In Phase III, Allovectin failed to perform better than the control (chemotherapy), and as a result Vical's stock price plummeted. Plaintiff alleges that Vical fraudulently misrepresented or omitted facts that cast serious doubts on Allovectin's prospects and materially misrepresented the timing of the release of Allovectin's Phase III clinical data.

Vical developed Allovectin as a novel immunotherapy designed to treat melanoma and potentially other cancers. FAC ¶ 37. At the time, immunotherapies were relatively unknown and presented unique challenges when compared with more traditional therapies. *Id.* at 38. Immunotherapy is intended to trigger an immune response to cancer cells, training the body's immune system to attack and eradicate cancers. *Id.* Because such treatments take time to train the immune system, this class of treatment is only used for cancer patients with strong immune systems who can withstand non-response for months before the treatment begins to take effect. *Id.* at 39.

Allovectin's Phase II trials proved promising. *Id.* at 40. Over the two-year trial (from 2001 to 2003), 11.8% of patients responded to the treatment. However,

sixty percent dropped out of the trial because the disease advanced before Allovectin could take effect. *Id.* The Phase II trials were conducted without a chemotherapy control. *Id.*

In 2004, Vical, in concert with the Food and Drug Administration ("FDA") designed a Phase III trial predicated on the results of Phase II. FAC ¶ 41. This Special Protocol Assessment ("SPA") outlined the "trial objectives and design, clinical endpoints and planned analyses expected to be needed for product approval." *Id.* The SPA limited enrollment in Phase III to patients who were "much less sick than patients enrolled in other melanoma studies and should be expected to live a long time with their disease." *Id.* at 42.

The SPA mandated interim safety reviews every six months. FAC ¶ 43. An independent safety monitoring committee would review the data from the study to ensure that Allovectin "did not create safety risks for patients." *Id.* The SPA also set both a primary and secondary endpoint. *Id.* at 45. The primary endpoint, "objective response rate," evaluated patients' response to treatment between 24 weeks and two years of the commencement of treatment. *Id.* The secondary endpoint, "overall survival," measured the mortality rate of patients receiving treatment. *Id.* at 46. The trial was scheduled to end after a set number of participants had succumbed to their disease.

To successfully meet the primary endpoint and accordingly achieve FDA approval, patients treated with Allovectin had to respond at least 10% more favorably than chemotherapy. FAC ¶ 47. Vical estimated that Allovectin would show a 13% response rate improvement over the control, chemotherapy. *Id.* Vical predicated their chemotherapy baseline on results from a previous Phase III study conducted by another pharmaceutical company. *Id.* at 48. This study included much sicker patients, and it was ultimately unsuccessful. *Id.*

During the Phase III trial, Vical repeatedly revised its potential end-date because participants were living longer than projected. Ultimately, the trial was not

completed until August 12, 2013. *Id.* at 169. Throughout the trial, Vical received the "death event" data but otherwise the study was blinded in separate third-party databases to be securely transferred to Vical. The data was un-blinded to both Vical and the public at the end of the study. *Id.* at 155. Plaintiffs could have un-blinded the response rate data (primary endpoint) earlier, but chose to un-blind both endpoints (the response rate and the overall survival rate) at the same time at the end of the study. *Id.*

A. Effect of Later-Approved Treatments

While the study was pending, Vical's officers periodically responded to questions from investors. Plaintiff challenges these responses as misleading or materially false. For example, during the Phase III study, the FDA approved two new melanoma drugs. FAC ¶12. These drugs proved to be highly successful at treating melanoma. *Id*. at 11–12, 50, 59. The question then arose as to whether these two new melanoma drugs were affecting the Phase III Allovectin study. Although Plaintiffs allege Defendants never disclosed the "significant problems" caused by the approval of these two new melanoma drugs, in fact the FAC is full of questions showing that the investors were aware of these new drugs and concerned about the impact they would have on the Allovectin study. In response, Defendants expressed optimism that the slowed death rate of the study was a result of the efficacy of Allovectin and was not affected by any of these new melanoma drugs. They based this optimism on the fact that "[t]he first time anybody could have gott [these later melanoma drugs] in the United States was — is some time in the April–May timeframe when it was formally approved. And then in Europe much later … Remember our last patient was recruited in the study in Feb 2010. That means these drugs were approved almost 15 months after our last patient was recruited." *Id.* at 96. Based on this assumption, Defendants believed that "any impact during the conduct of the trial of these drugs is likely very low. Post-approval, only Allovectin-7 patients who have lived long enough, they have gone

into and gotten those drugs, but the study is randomized." *Id.* at 108.

Throughout, Defendants were transparent about the basis for their opinions. Defendants primarily assumed, based on the blinded death event data, that by the time the newly-approved therapies were released, the control-chemotherapy patients had died. "And the fact that our [there are?] new therapies that are becoming available and maybe the patients are getting new therapies and maybe they're living longer. But let me remind you during the conduct of the study we doubt any of our parents [patients?] got any of these frontline therapies [because of the timing of the release of the new drugs as compared to the timing of the last patient enrolled in the Phase] so half of patients hopefully were dead by the time these new therapies were available." *Id.* at 147.

But ultimately, Defendants told the investors that, although they were hopeful, they could not know the impact of these two new drugs because the Allovectin study was blinded. "I don't know what—how widespread the usage [of the new melanoma drugs] is." *Id.* at 96. "But I don't know. We have no idea which patients post-approval are getting what, but that's the reason the study is randomized." *Id.* at 116.

B. Commercial Preparation

Plaintiff asserts that Vical's "minimal" commercial preparation belied Vical's officers' false optimism. CW2 states that the annual budget for 2013 did not include "significant development and manufacturing ramp up activities but instead only 'minimum' expenditures for such a ramp up, combined with a significant and deep cutting 'contingency plan.'" FAC ¶ 152. Vical had previously stated, after announcing that the study would not reach the projected death quota until later than expected:

> We're taking advantage of this additional time to advance self preparations for BLA filing and potential commercial launch and planning for Allovectin's success.

> In the manufacturing and regulatory areas for example, we are completing our commercial [ph] process characterization proceeding to validation of our manufacturing process as well as analytical validation. This will include producing consecutive conformance laws and commercial skills to demonstrate consistency and comparability with clinical launch to finalize the expiration date.
>
> We are also upgrading our data management systems in preparing for our electronic BLA submission. And our commercial preparations, we are securing our supply and distribution networks including validation of our selective contract, fill finish contract, manufacture operations, developing a comprehensive launch plan, detailed activity such as BLA submission, publication strategy, rising reimbursement, branding, distribution, identification of KOLs who'll support Allovectin-7.
>
> Some of these activities will extend beyond year-end, but we intend to make good progress by the time the data is released with the goal of filling the BLA at the earliest opportunity.

Id. at 114.

Plaintiff does not specifically allege how the "minimal" commercial preparation materially differs from the statements made to investors. There are no allegations in the FAC that the above-listed preparations did not take place.

C. Release of Results

On August 1, 2013, Samant provided a final status update to investors before Vical released the results of the Phase III trial. In it, he stated, "if results are positive Allovectin has the potential to become a first in class treatment alternative intended for outpatient administration with local injections designed to induce a systemic immune effect, we all hope for the best." FAC ¶ 164. Samant further stated:

> As we said, nothing has changed in our assumptions because sweep is a primarily involved in collection of data. So it should not have any impact on our assumptions and the control endpoint. As we said, the original assumptions which are in the trial design, 11 months of the control arm, and 18 months were treatment arm.
>
> We've said periodically that we believe that knowing what's occurred in the field that number could be anywhere in the 12 to 14

> months range and we feel very comfortable that if that's been control arm based on our prior Phase 2 data, the trial results will play out positively, but it all will be unblinded very shortly. So you will be able to see it all when that occurs.

Id. at 165.

On August 12, 2013, Vical issued a press release that announced the failure of Allovectin's Phase III trial. *Id.* at 169. Analysis showed that 17% of patients in the Allovectin arm of the study and 30% in the control arm had received a later-approved therapy as a "follow-on treatment" after completing Phase III. *Id.* at 173. Median survival rates for Allovectin-treated patients were roughly six months shorter than the control. *Id.* at 174.

II. LEGAL STANDARD

A motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the claims asserted in the complaint. Fed. R. Civ. P. 12(b)(6); *Navarro v. Block*, 250 F.3d 729, 731 (9th Cir. 2001). The court must accept all factual allegations pleaded in the complaint as true and must construe them and draw all reasonable inferences from them in favor of the nonmoving party. *Cahill v. Liberty Mutual Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir. 1996).

"The PSLRA [Private Securities Litigation Reform Act of 1995] significantly altered pleading requirements in private securities fraud litigation by requiring that a complaint 'plead with particularity both falsity and scienter.'" *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir. 2002) (quoting *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001)). Plaintiffs must first "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading and, if an allegation regarding the statement or omission is made on information and belief … state with particularity all facts on which that belief is formed." 15 U.S.C. 78u-4(b)(1).

Plaintiffs must next "allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *In re Daou Systems, Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005) (citing *In re Silicon Graphics Secs. Litig.*, 183 F.3d 970, 974 (9th Cir. 1999)). The Plaintiffs must also "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Gompper*, 298 F.3d at 895 (quoting 15 U.S.C. 78u-4(b)(1)). In general, a corporation's optimistic predictions do not rise to the level of false or misleading statements unless the plaintiff alleges facts supporting the inference that the predictions were known to be false or misleading at the time they were made. *Ronconi*, 253 F.3d at 430.

Although the court "must accept plaintiff's allegations as true and construe them in the light most favorable to the plaintiff," ultimately the court should review "the complaint in its entirety to determine whether the totality of facts and inferences demonstrate a strong inference of scienter." *Gompper*, 298 F.3d at 896. In *Gompper*, the Ninth Circuit considered the "inevitable tension" that arises between the different standards in Rule 12(b)(6) and that outlined in the PSLRA, concluding:

> Because we believe Congress made it crystal clear that the PSLRA's pleading requirements were put in place so that only complaints with particularized facts giving rise to a strong inference of wrongdoing survive a motion to dismiss … when determining whether plaintiffs have shown a strong inference of scienter, the court must consider all reasonable inferences to be drawn from the allegations, including inferences unfavorable to the plaintiffs.

Gompper, 298 F.3d at 897.

Generally, courts may not consider material outside the complaint when ruling on a motion to dismiss. *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1990). However, documents specifically identified in the complaint whose authenticity is not questioned by parties may also be considered. *Fecht v. Price Co.*, 70 F.3d 1078, 1080 n.1 (9th Cir. 1995)

(superseded by statutes on other grounds). Moreover, the court may consider the full text of those documents, even when the complaint quotes only selected portions. *Id.* It may also consider material properly subject to judicial notice without converting the motion into one for summary judgment. *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994).

As a general rule, a court freely grants leave to amend a complaint which has been dismissed. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986).

III. DISCUSSION[1]

In his first claim for relief, Plaintiff alleges that Vical and the individual defendants violated section 10(b) of the Securities Exchange Act and the related Rule 10b–5. Section 10(b) prohibits "any person ... [from] us[ing] or employ[ing], in connection with the purchase or sale of any security registered on a national securities exchange ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b–5 states: "It shall be unlawful for any person ... [t]o engage in any act, practice, or course of business which operates or would operate

[1] Both parties submit exhibits with their respective briefs. However, in evaluating a Rule 12(b)(6) motion, review is ordinarily limited to the contents of the complaint and material properly submitted with the complaint. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754 (9th Cir. 1994); *Hal Roach Studios*, 896 F.2d at 1555 n.19. The Court may also take judicial notice of certain items under Federal Rule of Evidence 201 without converting the motion to dismiss into one for summary judgment. *Barron*, 13 F.3d at 1377. Both parties fail to show that their respective exhibits are properly before this Court for the purposes of Defendants' motion to dismiss. Therefore, only those exhibits expressly noticed were considered to assess the merits of the arguments.

as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5(c).

In his second claim, Plaintiff asserts that the individual defendants violated section 20(a) of the Exchange Act, which makes certain "controlling" individuals also liable for violations of section 10(b) and its underlying regulations. However, both his first and second claim for relief is alleged against "all defendants."

In order to succeed on a section 20(a) claim, a plaintiff must properly plead an underlying section 10(b) violation. *See Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). Violating Rule 10b–5 requires five elements: "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *Id.* (quoting *In re Daou*, 411 F.3d at 1014) (internal quotation marks omitted).

As outlined in Plaintiffs' oral argument, the alleged material misrepresentations or misleading statements in the FAC fall into four categories. Each will be addressed in turn. Overall, none of the challenged statements is materially false or misleading, nor are there facts alleged in the FAC supporting scienter.

A. Defendants' "base assumptions were faulty"

Plaintiff first alleges the Defendants used faulty assumptions to make overly optimistic projections about the success of the Phase III trials. FAC ¶¶ 48, 106, 116, 130, 135. In hindsight, these assumptions proved incorrect. However, they were simply assumptions, and were characterized as such to investors. For example, Samant stated, "We believe that eight or nine months is what chemo gets [before mortality] and you would add about two plus months to, it will be an 11-month range for the kind of patients we are treating with. That's our guess, but that's the assumption that we have made in our statistical calculations for our survival endpoint. But there is no specific data available for our patient

population." FAC ¶ 98. These assumptions transparently stated their basis. Plaintiff claims these assumptions were based on faulty premises; this is true. However, at the time, these bases were the only available data. Plaintiff admits that the 60% dropout rate from Phase II was well-known to potential investors.[2]

The Complaint fails to allege any facts that would support an inference that Defendants knew these assumptions were faulty at the time they made the projections. In fact, since the study was blinded, all Defendants knew was that patients were not dying at the rate they anticipated. A logical inference was the Allovectin had been successful.

As part of the "faulty assumptions" allegations, Plaintiffs also allege that Defendants continually "delayed" their projection of the completion date while leading investors to believe the study would complete sooner than Defendants knew was actually possible. In hindsight, analysis revealed that the abnormally healthy participants and the introduction of later-approved effective therapies confounded the secondary endpoint predictions because they prolonged the participants' lives. However, as discussed above this does not rise to the level of a material misrepresentation nor are there any facts in the FAC supporting a strong inference that Defendants knew of any falsity at the time the statements were made.

B. Defendants knew patients in the Phase III trials were taking new melanoma drugs

Plaintiff next alleges that the end results were heavily skewed by the fact that patients in the Phase III trials were taking two new melanoma drugs. Plaintiff alleges Defendants knew the patients were taking the new melanoma drugs and

[2] "[P]reliminary results from a small Phase 2 clinical trial of the drug *left investors skeptical*. As with all immunotherapies, Allovectin can take several months after initial treatment to initiate a response in the body, which is too long for most melanoma patients to wait. A whopping 60% of patients in Allovectin's Phase 2 trial were forced to drop out before they could even complete their treatment because of disease progression." FAC ¶ 4 (italics added).

lied about it. FAC ¶¶ 50–52, 59, 96, 108, 147, 149.

First, Defendants told the investors that, although they were hopeful the new drugs would not skew the results, they did not know the impact of these two new drugs because the Allovectin study was blinded. *Id*. at ¶¶ 96, 116.

Furthermore, the Complaint fails to allege facts that would support the inference that Defendants knew the statements were false at the time they were made. Defendants assumed that the chemotherapy patients were, to confront the euphemisms head-on, dying off too rapidly to receive the newly approved medication. Similarly, it appears they reasoned that if Allovectin was as successful as they optimistically believed, there was no need for the Allovectin arm of the trial to resort to the new treatments, or that Allovectin had proved itself effective before the participants began alternative therapies. FAC ¶ 108 "Post-approval, only Allovectin-7 patients who have lived long enough have gone into and gotten those drugs[.]" *Id.* at 108. Accordingly, they repeatedly opined that the effect of new melanoma therapies did not affect the death rate or the trial generally. However, contrary to Plaintiff's assertions, it is clear that investors were aware of the possibility that long-lived patients received other therapies. Although the premise that only Allovectin patients were long-lived was incorrect, it was a reasonable assumption based on the blinded death rate data.

C. Defendants hid and misrepresented attempts to change the endpoints with the FDA

Plaintiff alleges that Defendants misled investors by failing to disclose any discussions about changing endpoints with the FDA. FAC ¶¶ 116, 126. The Court takes judicial notice of the full text of Samant's comment in response to an investor's question about changing endpoints (quoted in part at FAC ¶ 126): "Well, we have to spend money on adjudicating the data [on the primary endpoint] because remember our SPA is still valid with the agency and, in that SPA, response rate is the primary endpoint. And if we don't adjudicate, we'll be in

violation of the SPA. So the agency has told us to stick with the current statute of the SPA and that's why we're sticking with the statute of the SPA." Vical, Inc. Q1 2012 Earnings Call Tr. 38, ECF 39-4. Samant's statement is not false or misleading, in context.

D. Defendants were internally planning for failure while misrepresenting to the market they were planning for success

Plaintiff claims that Defendants falsely stated to investors that Vical was preparing for commercialization of Allovectin, when in fact Vical was only taking "minimal" steps necessary for a commercial launch. FAC ¶¶ 19–20, 70–74, 114, 124, 157. Although commercially exploiting a new product as soon as is practical is in both a company's and its investor's best interests, officers should attempt to be prudent in their allocations. It is entirely prudent to take "minimal" steps towards commercialization, and Plaintiff does not allege Defendants took *no steps* towards commercial preparation. Without alleging that no steps were taken, Defendants statements are not materially false or intentionally misleading.

IV. CONCLUSION & ORDER

Ultimately, investments in experimental drugs are inherently speculative. Investors cannot, after failing in this risky endeavor, hedge their investment by initiating litigation attacking perfectly reasonable—if overly optimistic—statements proved wrong only in hindsight. At all turns, Defendants clearly stated the bases for their opinions and denoted them as such. Punishing a corporation and its officers for expressing incorrect opinions does not comport with Rule 10b–5's goals. Accordingly, the Court **GRANTS** Defendants' motion to dismiss. ECF 39. The Court **DISMISSES WITHOUT PREJUDICE** this matter and the consolidated case. The Court **TERMINATES AS MOOT** Defendants' motion to strike (ECF 37) and *ex parte* application for leave to file related supplemental authority (ECF 48).

The Court gives the Plaintiffs **LEAVE TO AMEND** the FAC. If Plaintiffs intend to file a Second Amended Complaint, they must do so **on or before March 25, 2015**. However, Plaintiffs are cautioned that any amended Complaint must allege specific misstatements beyond overly optimistic projections couched in speculative terms and must allege facts supporting a strong inference that Defendants knew the statements were false at the time they were made, not with the benefit of hindsight. If Plaintiffs choose to amend, they are directed to the new local rule requiring an amended complaint to highlight or interlineate changes made to the new complaint.

Dated: March 9, 2015

Hon. Cynthia Bashant
United States District Judge